American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

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February 26, 2010

Kristina A. Thayer, PhD
Acting Director
Center for the Evaluation of Risks to Human Reproduction
National Institute of Environmental Health Sciences
P.O. Box 12233, MD K2-04
Research Triangle Park, NC 27709

Dear Dr. Thayer,

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates the opportunity to comment on the final expert panel report evaluating the developmental toxicity of soy infant formula.

The AAP strongly supports stringent examination of the safety and efficacy of all types of infant formula. A robust regulatory framework is vital because formula serves as the exclusive source of nutrients and calories for formula-fed infants. Even after complementary foods are introduced into the infant's diet, the majority of the infant's nutrition continues to be received through formula until weaning.

Soy protein-based formulas have been available for almost 100 years. Despite very limited indications for their use, soy protein-based formulas may account for more than 20 percent of formula used in the United States[1]. Because soy infant formula contains a number of unique components, it is necessary to continue to study the effect of its components and structure on infants and children throughout their development.

Of the many ingredients and factors present in soy formulas, phytoestrogens are of particular interest in human health. Phytoestrogens consist of several groups of nonsteroidal estrogens, including isoflavones, which are commonly found in legumes. Concerns have been raised in relation to the safety of phytoestrogens and isoflavones, including their potential negative effects on sexual development and reproduction, neurobehavioral development, immune function, and thyroid function. At the same time, some studies have suggested a protective effect of isoflavones against a number of adult chronic diseases, including coronary heart disease and breast, endometrial, and prostate cancers.

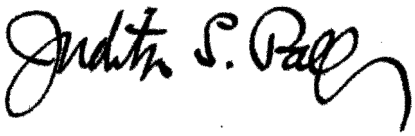
As science has advanced, our understanding of the complexity of human development and nutrition has also grown. AAP appreciates that the Center for the Evaluation of Risks to Human Reproduction (CERHR) has revisited the potential developmental and reproductive toxicities of soy infant formula. Since the first expert panel was

convened in 2006, a number of new studies have been published related to human exposure, reproductive toxicity, and developmental toxicity for soy infant formula. AAP supports updated evaluations of the data on soy infant formula and the potential developmental toxicity of its major isoflavone components, including genistein, daidzein and glycitein.

Although there is evidence for adverse effects from individual components of soy protein in animal models in dosages equivalent to human exposure as summarized by the expert panel, the existing data available on human infants does not allow assessment of adverse risk from soy protein exposure as currently fed in soy protein-based infant formulas. At this time, there inadequate evidence in humans to allow us to state that dietary soy isoflavones and phytoestrogen may adversely affect human development, reproduction or endocrine function. As more data become available, risks may be addressed in a more comprehensive fashion. At the current time, the risks as outlined are considered negligible.

Please note that AAP Committee on Nutrition Chairman Jatinder Bhatia, MD FAAP recused himself from the review of this document and development of comments due to his service on the expert panel. In closing, the American Academy of Pediatrics appreciates the opportunity to provide comment and input on the final expert panel report on soy infant formula. If the AAP may provide further assistance or information, please contact Cindy Pellegrini in the Academy's Washington Office at 202/347-8600. We look forward to continuing to work together to improve the health of our nation's infants and children.

Sincerely,



Judith S. Palfrey, MD FAAP
President

JSP:km

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[1] Bhatia J. Greer F. Use of Soy Protein-Based Formulas in Infant Feeding. *Pediatrics* 2008; 121: 1062-1068.